medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

[51 FR 36951, Oct. 16, 1986, as amended at 59 FR 61786, Dec. 2, 1994]

§ 35.920 Trainino for imaging and localization studies.

Except as provided in §35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in §35.200(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiopharmaceutical chemistry; and

(v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) Calculating and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent the misadministration of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes:

(i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient or human research subject followup; or

(c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

[51 FR 36951, Oct. 16, 1986, as amended at 59 FR 61786, Dec. 2, 1994]

§ 35.930 Training for therapeutic use of unsealed byproduct material.

Except as provided in §35.970, the licensee shall require the authorized user of radiopharmaceuticals in §35.300 to be a physician who:

(a) Is certified by:

(1) The American Board of Nuclear Medicine;